TO: **Parties Concerned with the Rules Relating to Immunization Requirements for Healthcare Workers, 10-144 Chapter 264**

FROM: **Dr. Dora Mills, MD, Director, Maine Bureau of Health, Department of Human Services**

DATE: **October 7, 2002**

SUBJECT: **Immunization Requirements for Healthcare Workers**

In April 2002, the Maine Department of Human Services, Bureau of Health adopted rules pursuant to 22 M.R.S.A. § 802 governing Immunization Requirements of Healthcare Workers (hereinafter known as the "HCW Rule" or "Rule"). In general, the purpose of the Rule is to prescribe the dosage for required immunizations and define responsibilities, exclusion periods, record keeping and reporting requirements for officials of hospitals and designated healthcare facilities. The Rule was developed based primarily on the December 26, 1997 issue of the Morbidity and Mortality Weekly Report (MMWR) published by the Centers for Disease Control and Prevention. The complete MMWR article can be found on the internet at: http://www.cdc.gov/mmwr/preview/inhd97_rr.html. Relevant sections of the Occupation Safety and Health Administration (OSHA) regulations are also incorporated into the Rule.

It is our hope that this memo will clarify many of the issues that have been raised since the Rule was promulgated. **This memo supersedes all correspondence disseminated by the Department prior to the date above.** Following is a summary of frequently asked questions and concerns, and the Department's responses to those concerns.

What facilities does the Rule apply to?

The new legislation expanded the definition of "Designated Healthcare Facility" to include many new types of facilities which previously were not included. The definition reads as follows:

> "Designated Healthcare Facility" means a licensed nursing facility, residential care facility, Intermediate Care Facility for the Mentally Retarded (ICF/MR), multi-level health care facility, hospital, or home health agency.

The Rule applies to all the facilities listed under the definition, but some clarification is needed. The rule was not intended to include Level 1 residential care facilities, nor was it intended for small Private Non-Medical Institutions. Enforcement under this section will be performed by the Bureau of Health, and no enforcement activities will take place in facilities with six (6) or fewer beds. Furthermore, as provided under section 8 of the Rule, "Designated healthcare facilities under this section shall be allowed up to one year from the effective date of this rule to ensure that all employees are in compliance with the requirements herein."

Are facilities that provide only outpatient services required to comply with the HCW Rules?

Facilities that are outpatient based are not required to comply with the HCW Rules. However, if the outpatient facility is associated with a larger inpatient facility and has employees who may float between the two facilities, they are required to comply with the Rules.

Are Designated Healthcare Facilities required to report the immunization status of employees?

Yes, the HCW Survey is a required report designated in Section 7(D) of the rules, which states "The chief administrative officer of each designated healthcare facility is responsible for submitting a summary report in the immunization status of all employees on a form prescribed by the department, to the Director of the Bureau of Health of the Department of Human Services." The annual survey is typically sent out in the month of November with a required return date of December 15.

Which employees need to comply with the Rule, and are students and volunteers that work in a facility required to comply with the Rule?

Page 2 of the HCW Rule defines "Employee" as "a person who performs a service for wages ro other remuneration for a designated health facility." This includes each and every employee within a designated facility but, as the Rule indicates, the need to show proof of immunity for the specific diseases depends on the level of care the employee provides. For example, according to the MMWR referenced above, "Because any HCW (i.e., medical or non medical, paid or volunteer, full time or part time, student or non student, with or without patient-care responsibilities) who is susceptible can, if exposed, contract and transmit measles or rubella, all medical institutions (e.g., inpatient and outpatient, public and private) should ensure that those who work within their facilities are immune to measles and rubella. The same level of discretion should be taken for Varicella, also transmissible via respiratory droplet.

As for Hepatitis B and influenza (as indicated under sections 2-B and 2-C respectively), the need to immunize depends on the individual employee's risk for occupational exposure, and whether or not the employee provides direct patient care. The Department supports these recommendations and strongly urges facilities to adopt such a policy with regard to students and volunteers as well.

The Rule states that employees who provide direct care to "residents" of the facility should be offered annual immunizations against influenza. Does this mean the Rule only applies to employees of a facility where there are "residents," and which employees are considered "at risk?"

The Rule applies to all facilities listed under the definition of Designated Healthcare Facility, regardless whether or not the facility refers to its clients as residents. As the Rule states, all personnel who provide direct care should be offered annual immunization against influenza. This includes administrative and home care personnel who provide direct patient care.

Are employees who do not have direct patient care required to have all the immunizations?

Employees who do not have direct patient care *are* required to have proof of immunity for Measles, Mumps, Rubella, and Varicella (except for office staff of Home Care Agencies that do not have contact with patients). As these are "airborne" diseases, all employees in the facility are at risk. Employees with no direct patient care are not required to provide proof of immunity against Hepatitis B and, as stated in Section 2-C of the Rule, personnel who provide direct care should be offered annual immunization against influenza.

Who is responsible for ensuring staff provided by temporary agencies have had the required immunizations?

The Department adopts the prevailing OSHA Standard governing Hepatitis B vaccination to all the immunizations required under the Rule. If the employee is on the payroll of the temporary agency firm, even though the healthcare facility (i.e., host employer) exercises day-to-day supervision over the employee, the temporary agency is responsible for ensuring appropriate vaccination and/or post-exposure evaluation and follow-up. According to the OSHA Standard, "the host employer's obligation is to take reasonable measures to assure that the personnel service firm has complied with these provisions." The Department has agreed to work with the healthcare facilities to help educate the temporary agencies with regard to these regulations.

Must employees provide evidence of immunity to mumps?

While proof of immunity to mumps is not mandated, it is highly desirable for all Healthcare Workers. This is consistent with the MMWR upon which the Rule is based.

What is considered acceptable evidence of immunity with regard to Measles, Mumps, and Rubella?

According to the MMWR, "Persons born in 1957 or later can be considered immune to measles, mumps, or rubella only if they have documentation of a) physician-diagnosed measles, mumps disease; or b) laboratory evidence of measles, mumps, or rubella immunity (persons who have an "indeterminate" level of immunity upon testing should be considered non immune); or c) appropriate vaccination against measles, mumps, and rubella (i.e., administration on or after the first birthday of two doses of live measles vaccine separated by greater than or equal to 28 days, at least one dose of live mumps vaccine, and at least one dose of live rubella vaccine). An employee or family member's recollection of an employee having the disease (i.e., self reporting) is not considered a reliable history for measles, mumps, and rubella.

What about employees born before 1957?

Employees born before 1957 do not need to provide documented evidence of immunity to measles and rubella. According to the MMWR, "Although birth before 1957 generally is considered acceptable evidence of measles and rubella immunity, health-care facilities should consider recommending a dose of MMR vaccine to unvaccinated workers born before 1957 who are in either of the following categories: a) those who do not have a history of measles disease or laboratory evidence of measles immunity, and b) those who

lack laboratory evidence of rubella immunity. Rubella vaccination or laboratory evidence of rubella immunity is particularly important for female HCWs born before 1957 who can become pregnant. The Department urges facilities to adopt such recommendations.

What is considered "reliable history" of disease for Varicella?
According to the MMWR, "A reliable history of chickenpox is a valid measure of VZV immunity. Serologic tests have been used to assess the accuracy of reported histories of chickenpox (76,80,93,95-97). Among adults, 97% to 99% of persons with a positive history of varicella are seropositive. In addition, the majority of adults with negative or uncertain histories are seropositive (range: 71%-93%). Persons who do not have a history of varicella or whose history is uncertain can be considered susceptible, or tested serologically to determine their immune status. In health-care institutions, serologic screening of personnel who have negative or uncertain history of varicella is likely to be cost effective." Thus, self-reporting for varicella is acceptable for employees who are certain of their disease history. It should be noted, however, that the most reliable history of disease is that which is confirmed by a physician.

Furthermore, the risk of complications from varicella is greater among adults, particularly for those who are immunocompromised. The most frequent complications in immunocompromised persons are pneumonia and encephalitis. Adults account for only 5% of reported cases of varicella, but account for approximately 35% if mortality. For these reasons we urge facilities to confirm employees' immunity to varicella to the greatest extent possible.

What is required on the Certificate of Immunization?
According to section 7(B) of the Rule, "The immunization status of each employee with regard to each disease shall be noted on the employee's health record. The health record of each employee shall include at a minimum the month and year that each immunizing agent was administered." This is not the same level of documentation required when one records the administration of a vaccine for the first time (i.e., manufacturer, lot number, expiration date, route, site, etc.)

Are school records acceptable?
School records can be used for reliable history of disease and for proof of immunization, providing they include, at a minimum, the month and year of administration required for the employee record. The underlying assumption for accepting school records and is that the information was in fact, at some point, certified by the employee's attending physician.

What about computerized records?
Computerized records will be acceptable in the same way school records are, providing they include, at a minimum, the month and year of administration required for the employee record. Efforts should be made to have original documentation whenever possible.

Are facilities required to document an employee's immunization status for influenza?

Documentation of individual flu vaccination is recommended but not required. According to section 2-C of the Rule, "all Designated Healthcare Facilities shall adopt a policy that recommends and offers annual immunizations against influenza to all personnel who provide direct care to residents of the facility."

Should a serology be done on employees who completed the Hepatitis B series years ago but did not have the follow-up serology?
The current CDC guidelines regarding Hepatitis B states those employees who have ongoing contact with blood or body fluids and are at ongoing risk for percutaneous injuries are to be tested for antibody to Hepatitis B surface antigen, one to two months after the completion of the three-dose vaccination series. Employees who do not respond to the primary vaccination series must be revaccinated with a second three-dose vaccine series and retested, unless they are HbsAg-positive (infected). Non-responders must be medically evaluated.

Employees who have completed the series but were not tested within the 1-2 month window do not need to be routinely tested. However, employees at ongoing risk for exposure may receive one additional dose followed by the 1-2 month test for antibodies. If immune memory is present, the exposure to the surface antigen in the vaccine will stimulate the anamnestic memory and the titer will rise giving a positive result. If this occurs, the positive result can be documented and no further testing or boosters would be indicated.

Section 7-D of the Rule requires facilities to submit a summary report on the immunization status of all employees, including those who are out of compliance. Does this mean employees can be non-compliant and still be at work?
No. While the language under 7-D should have been crafted with greater precision, section 2-D clearly states that "No chief administrative officer may permit any employee to be in attendance at work without a certificate of immunization for each disease or other acceptable evidence of immunity to each disease, or documentation of exemption or declination."

Pursuant to section 7-D of the Rule, will BOH staff need to get special consent from HIPPA to conduct periodic auditing of employee health records?
BOH staff have been advised that they do not need special consent. However they would still have to protect any information they viewed and/or took from the employer site if there were any patient identifiers in it. The employee is the same as a patient under HIPAA so you have to protect their information. The employer must protect it as well.